

What is claimed is:

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1. A method for detection, differentiation and quantification of free and encapsulated target nucleic acids in a sample comprising:
determining a total target nucleic acid content in said sample,
adding a nuclease to said sample to digest free target nucleic acids in said sample to form a digested sample;
determining a total target nucleic acid remaining in said digested sample; and
quantifying the total amount of free target nucleic acid in said sample by subtraction of said determined target nucleic acid content in said digested sample from said determined target nucleic acid content in said sample.
 2. The method of claim 1 wherein said determining of said target nucleic acids is performed using a nucleic acid amplification assay.
 3. The method of claim 2 wherein said nucleic acid amplification assays is a polymerase chain reaction (PCR) assay or a reverse transcriptase (RT) PCR assay.
 4. The method of claim 1 further comprising adding nucleic acid standard to said sample before said first total target nucleic acid content is determined.
 5. The method of claim 1 further comprising adding nucleic acid standard to said sample after free target nucleic acid in said sample are digested with said nuclease.
 6. The method of claim 1 wherein said nuclease is inactivated after said free nucleic acids in said sample are digested.
 7. The method of claim 1 wherein said nuclease is DNase or RNase.
 8. The method of claim 1 wherein said sample is selected from the group consisting of blood, plasma, serum, cell culture fluids, cells, and a pharmaceutical preparation.
 9. A pharmaceutical preparation tested for infectious pathogens using the methods of claim 1.

10. A method for determining and controlling virus inactivation rates of a virus inactivation processes comprising:
preparing a sample having a known concentration of a target virus to be inactivated;
performing a target virus inactivation process;
determining a total of target virus nucleic acid content in said sample,
adding a nuclease to said sample to digest free target virus nucleic acids in said sample to form a digested sample;
determining a total target virus nucleic acid content in said digested sample; and
quantifying the total amount of free target virus nucleic acid in said sample by subtraction of said determined target virus nucleic acid content in said digested sample from said determined target virus nucleic acid content in said sample.
11. The method of claim 10 wherein said determining of said target nucleic acids is performed using a nucleic acid amplification assay.
12. The method of claim 11 wherein said nucleic acid amplification assays is a polymerase chain reaction (PCR) assay or a reverse transcriptase (RT) PCR assay.
13. The method of claim 10 further comprising adding nucleic acid standard to said sample before said first total target nucleic acid content is determined.
14. The method of claim 10 further comprising adding nucleic acid standard to said sample after free target nucleic acid in said sample are digested with said nuclease.
15. The method of claim 10 wherein said nuclease is inactivated after said free nucleic acids in said sample are digested.
16. The method of claim 10 wherein said nuclease is DNase or RNase.
17. The method of claim 10 wherein said sample is selected from the group consisting of blood, plasma, serum, cell culture fluids, cells, and a pharmaceutical preparation.
18. An infectious pathogen inactivation process validation method comprising:
providing a biological sample;
adding an infectious agent to said biological sample to form a spiked sample;

exposing said spiked sample to an infectious agent inactivation procedure forming an inactivated spiked sample;

quantifying infectious agent nucleic acid content in said inactivated spiked sample;

adding a nuclease to said inactivated spiked sample to form a digested inactivated spiked sample;

quantifying said infectious agent nucleic acid content in said digested inactivated spiked sample.

19. The method of claim 19 further comprising subtracting said digested inactivated spiked sample's infectious agent nucleic acid content from said inactivated spiked sample's infectious agent nucleic acid content.

20. The method of claim 18 further comprising using a quantitative polymerase chain reaction assay to quantify said infectious agent nucleic acid content.

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